CORE CENTERS FOR MUSULOSKELETAL DISORDERS

RELEASE DATE: November 21, 2002

RFA: AR-03-004

National Institute of Arthritis and Musculoskeletal and Skin Diseases
(NIAMS)
(http://www.niams.nih.gov)

LETTER OF INTENT RECEIPT DATE: April 13, 2003

APPLICATION RECEIPT DATE: May 13, 2003

THIS RFA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS RFA

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for research core centers (P30s) for musculoskeletal disorders. The Core Centers for Musculoskeletal Disorders (CCMDs) will provide the resources for a number of established,

currently funded investigators, often from different disciplines, to adopt a multidisciplinary approach to common research problems in musculoskeletal disorders and to ensure greater productivity than from each of the separate projects.

RESEARCH OBJECTIVES

Research in musculoskeletal disorders is at a stage where a number of areas are making broad advances that can be effectively fostered by research core centers. Examples of these areas include, but are not limited to:

o Regulation of skeletal growth and remodeling by systemic and local factors; diagnostic markers of skeletal remodeling; genetic basis of skeletal morphogenesis, growth, and disease.

o Mechanisms of bone repair and regeneration, including fracture healing; development of techniques for growth plate repair, reconstitution of large defects, and limb lengthening, including use of autografts and allografts, and distraction osteogenesis.

o Mechanisms of cartilage repair and regeneration, including chondroprogenitor cell biology, genetics, and biomechanical signaling; development of techniques for chondroprotection and repair of the articular surface, including gene therapy approaches.

The investigators make the choice of research area upon which the CCMD would focus.

The CCMDs will provide support for:

1. Core resources and facilities to be used by investigators of individually supported research projects in order to enhance and coordinate their activities. This support may include personnel, equipment, supplies, services, and facilities.

2. Up to $100,000 yearly in direct costs for pilot and feasibility studies.

3. Program enrichment activities.

4. Administrative Core

A CCMD should be an identifiable organizational unit within a university-affiliated medical center. An Administrative Core should be proposed to coordinate the Center and administer the program

enrichment activities. Two or more research cores must be proposed. A research core is a facility shared by two or more Center investigators that enables them to conduct their independently funded individual research projects more efficiently and/or more effectively. Cores generally fall into one of four categories: (1) provision of a technology that lends itself to automation or preparation in large batches (e.g., histology and tissue culture); (2) complex instrumentation (e.g., electron microscopy); (3) animal preparation and care; and (4) service and training (e.g., molecular biology, biostatistics); (5) genetics/sequencing and (6) bioengineering.

A pilot and feasibility study program provides modest research support ($20,000 - $50,000 yearly) for a limited time (1 to 3 years) to enable eligible investigators to explore the feasibility of a musculoskeletal disorders-related concept and amass sufficient data to pursue it through other funding mechanisms. An investigator is eligible only once every 5 years. Eligible investigators include:

1. An established investigator in musculoskeletal disorders or related areas with a proposal for testing the feasibility of a new or innovative idea that is musculoskeletal disorders-related but represents a clear and distinct departure from the investigator's ongoing research interest;

2. An established, supported investigator with no previous work in musculoskeletal disorders or related areas who is willing to test the applicability of his/her expertise on a musculoskeletal disorders-related problem; and

3. A new investigator who has not been a principal investigator in a past or current NIH research project grant (R01, R29, P01) or a current R55 grant. New investigators should be clearly independent and have a faculty appointment higher than that of postdoctoral fellow or research associate.

Applicants from institutions which have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. Details of the interactions of the CCMD staff with the GCRC staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the GCRC Program Director must be included with the application.

MECHANISM OF SUPPORT

This RFA will use NIH P30 award mechanism. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. This RFA is a one-time solicitation. Future competing-continuation applications based on this project will be the subject of a future RFA. The anticipated award date is April 1, 2004.

This RFA uses just-in-time concepts.

FUNDS AVAILABLE

NIAMS intends to commit approximately $1.2 million in FY 2004 to fund up to 2 new and/or competing-continuation grants in response to this RFA. An applicant should request a project period of 5 years and a budget for direct costs of up to $400,000 per year. Although the financial plans of the NIAMS provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

o For-profit or non-profit organizations
o Public or private institutions, such as universities, colleges, hospitals, and laboratories
o Faith-based or community-based organizations.

Applications from foreign institutions will not be accepted.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

The director and co-director should budget for an annual one-day meeting in Bethesda, MD with NIAMS staff.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

The Guidelines for Core Centers are available at:
http://www.niams.nih.gov/rtac/funding/grants/sdrcwww.htm

General information about the NIAMS Core Center Program may be found at:
http://www.niams.nih.gov/rtac/funding/grants/centers_programs.htm#P30

o Direct your questions about scientific/research issues to:

Dr. Julia B. Freeman
Centers Program, EP,
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Boulevard, Suite 800
Bethesda, MD 20892-4872 (20817 for courier service)
Telephone: (301)-594-5053
FAX: (301)-480-4543
Email: freemanb@exchange.nih.gov

o Direct your questions about peer review issues to:

Dr. Cheryl A. Kitt
Director, Extramural Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Boulevard, Suite 800
Bethesda, MD 20892-4872 (20817 for courier service)
Telephone: (301) 594-2463
FAX: (301) 480-4543
Email: kittc@mail.nih.gov

o Direct your questions about financial or grants management matters to:

Melinda Nelson
Chief Grants Management Officer, GMB
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Boulevard, Suite 800
Bethesda, MD 20892-4872 (20817 for courier service)
Telephone: (301) 435-5278
FAX: 301-480-5450
Email: nelsonm@exchange.nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

o Descriptive title of the proposed research
o Name, address, and telephone number of the Principal Investigator
o Names of other key personnel
o Participating institutions
o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Dr. Julia B. Freeman
Centers Program, EP,
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Boulevard, Suite 800
Bethesda, MD 20892-4872 (20817 for courier service)
Telephone: (301)-594-5053
FAX: (301)-480-4543
Email: freemanb@exchange.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

SUPPLEMENTAL INSTRUCTIONS: The Guidelines for Core Centers are available at: http://www.niams.nih.gov/rtac/funding/grants/sdrcwww.htm

General information about the NIAMS Core Center Program may be found at: http://www.niams.nih.gov/rtac/funding/grants/centers_programs.htm#P30

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/label-bk.pdf.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center For Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Boulevard, Suite 800

Bethesda, MD 20892-4872 (20817 for courier service)

APPLICATION PROCESSING: Applications must be received by the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIAMS. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

o Receive a written critique
o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
o Receive a second level review by the NIAMS National Advisory Council.

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

o Significance

o Approach
o Innovation
o Investigator
o Environment

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

o PROTECTIONS: The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

o INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

o DATA SHARING: The adequacy of the proposed plan to share data.

o BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

o OTHER REVIEW CRITERIA

Applicants should clearly demonstrate the ways in which the CCMD will build the local research program, will support on-going projects and will attract both senior and new investigators to research in musculoskeletal disorders. Review criteria that will be used by the initial review group (IRG) in the evaluation of the Core Center applications follow:

1. Evaluation of Cores

A research core is evaluated on the facilities and/or services provided. Important factors include:

Significance: Will the core have utility to the Core Center research base (minimum: two independently funded investigators)?

Approach: Are the quality of services high? Are there procedures for quality control? Is the core cost effective? How is cost reimbursement proposed?

Innovation: Will the core likely promote interdisciplinary research?
Are unique services offered?

Investigator: Are the personnel appropriate?

Environment: Are the facilities and equipment adequate? Is there institutional commitment to the core?

2. Evaluation of Pilot and Feasibility Studies (P&Fs)

For individual P&Fs:

Significance: Will the proposed work likely yield meaningful preliminary data leading to a research proposal?

Approach: Are the experimental approaches adequate?

Innovation: Is the research topic one that promotes innovative new research related to the core center?

Investigator: Does the investigator meet one of the criteria for P&F investigators? (If not, the project should not be considered further.)

Environment: Is the project appropriate to the research base of the core center? Does one or more of the cores offer needed materials/assistance?

3. Evaluation of the Administrative Core

The Administrative Core is evaluated on the leadership provided. Important factors include:

Significance: Does the proposed Core Center document coordination of ongoing research between the separately funded projects and the Core Center including mechanisms for internal monitoring?

Approach: Is the management proposed appropriate for 1) fiscal administration, procurement, property and personnel management, planning, budgeting, etc.; 2) reviewing the use of, and administering funds for, the pilot and feasibility program? Are the Core Center budgets appropriate for the proposed and approved work to be done in core facilities, for pilot and feasibility studies, and for enrichment in relation to the total Core Center program?

Innovation: Is there a plan for the establishment and maintenance of internal communication and cooperation among the Core Center investigators and for an enrichment program that provides outside review and input?

Investigators: Is there scientific and administrative leadership, commitment and ability, and adequate time commitment of the Core Center Director and Associate Director for the effective management of the Core Center program?

Environment: Have institutional lines of authority and sanction been documented for the Core Center?

4. Overall Core Center Evaluation

An overall priority score will be assigned to the application. This score will reflect not only the quality of the cores, administration, and pilot and feasibility studies, but also the quality of the research base and how the proposed Core Center will enhance the research base.

The following elements will be evaluated:

a. The scientific excellence of the Core Center's research base as well as the relevance and interrelation of these separately funded research projects to the central themes of the Core Center and the likelihood for meaningful collaboration among Core Center investigators. Existence of a base of established independently supported biomedical research of high quality is a prerequisite for establishment of a Core Center.

b. The application must convey how the proposed Core Center will enhance significantly the cited research base established at the host institution. In a competing continuation application, the application should document an impact of the Core Center. This includes the qualifications, experience, and commitment of the Core Center investigators and their willingness to interact with each other. This also includes efficient and effective use and/or planned use of enrichment

funds including the contribution of these activities in enhancing the realization of the Core Center concept.

c. The appropriateness, quality and relevance of the proposed cores, and the modes of operation, facilities, and potential for contribution to ongoing research.

d. The proposed management of the pilot and feasibility program and the scientific merit of the pilot and feasibility projects for which funds are requested from the Core Center grant. The effectiveness of the proposed program will serve as a basis for recommendations concerning the level at which pilot and feasibility studies will be supported throughout the project period.

e. The overall environment for a Core Center. This includes the institutional commitment to the program, including lines of accountability regarding management of the Core Center, and the institution's partnership with the Core Center, and the institutional commitment to individuals responsible for conducting essential Core Center functions. This also includes the academic environment and resources in which the activities will be conducted, including the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and schools.

Since the NIAMS is interested in funding only the best research, individual components of lesser quality may not be funded, even if approved, under the "umbrella" of the Core Center grant mechanism. It is primarily for this reason that each component will be assigned a separate merit rating, taking into consideration only its merit as an individual pilot and feasibility study or core.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: April 13, 2003
Application Receipt Date: May 13, 2003
Peer Review Date: October/November 2003
Council Review: January 2004
Earliest Anticipated Start Date: April 1, 2004

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

o Scientific merit (as determined by peer review)

o Availability of funds
o Programmatic priorities.

REQUIRED FEDERAL CITATIONS

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.
The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://grants.nih.gov/grants/stem_cells.htm and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html.
Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide the official NIH identifier(s)for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants

should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at http://grants.nih.gov/grants/policy/policy.htm and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Return to Volume Index
Return to NIH Guide Main Index